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# Conflict of Interests in Biomedical Research: Beyond Disclosure

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# Conflict of Interests in Biomedical Research: Beyond Disclosure

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Imagine that you are a member of a committee at your institution whose job is to oversee conflicts of interest in biomedical research. While this is sometimes done by the Institutional Review Board (IRB), many institutions, including yours, began separate conflict of interest committees within the last decade. Your committee has some fairly standard procedures regarding your operations and how you judge the activities of investigators who report income that requires oversight by your group. A typical situation that your group reviews might involve an investigator who is conducting research sponsored by a private pharmaceutical or device company. The investigator's research could be any of a variety of types, from participating in a clinical trial of a new medication to testing a new device that is surgically implanted. Furthermore, this research can be at various phases of development from a pilot study to determine the initial safety of a device or medication to a later phase study in which the efficacy and market worthiness of the research intervention is being determined.

You review the information that that the investigator submitted to your committee and it shows that he has had a long-term relationship with this sponsor that is known to you to have been fruitful in terms of funding and publication. You note that in the past year he did a fair amount of "consulting" work for this company and also has done some lecturing on their behalf. He has done this kind of work for the company before and the amount of money he receives in compensation varies from year to year but is typically slightly less than the annual threshold your institution uses to prohibit investigators from conducting research sponsored by that company, perhaps $20,000 or so. After a brief discussion of your committee, a motion is put forward to require that the investigator disclose this relationship to potential enrollees in the consent form. The motion carries. Having now received approval of the conflict-of-interest committee, his application is sent on to the Institutional Review Board (IRB) for the next step in the approval process for all research involving human subjects.

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## I. WHAT'S THE PROBLEM?

There are many possible reasons for concern in this scenario, and a rapidly growing body of significant literature on conflicts of interest in biomedical research is developing. This literature is beginning to illuminate the many concerns we may have about these conflicts and the various motives in requiring these disclosures. For instance, we may wish to simply promote trust among the potential research participants by not withholding such information. Or, we may think that the financial relationships could potentially pose a risk to the subjects and that they should receive this information in order to appropriately protect themselves. Or, perhaps more despondently, we may think that it is all that we can do. I will focus on the latter. In particular, I believe that there is an increasing recognition that these gratuities compromise the integrity and professionalism of the medical and research professions and that we cannot ameliorate simply by informing potential research subjects.[1]

With the passage of the Bayh-Dole Act (1980), a great deal of money from private industry has flowed into academic medicine, especially in the form of sponsored research. But, beyond simply sponsoring research studies, a significant amount of money flows to researchers in the form of consulting and speakers fees, fees for recruitment of subjects to research studies, and through equity interests of various kinds such as stock in the sponsoring company or patent royalties. In general, universities have focused their conflict of interest management strategies in areas that generate, or have the potential to generate, very large sums of money. Institutions have typically asked researchers to report income and revenue from a corporate entity once it exceeded a certain annual amount, e.g., $10,000. In general, the assumption behind such thresholds for reporting has been that the amount of monetary gain would have to be quite large relative to a physician's salary to pose any real risk to the integrity of the science or the human subjects involved. When large equity interests or patents are at stake, conflict of interest committees or IRBs often add protections such as appointing individuals or boards to monitor the data in order to safeguard the integrity of the science.

Recent years have seen more attention paid to the lower end of the monetary scale. Many esteemed groups that have put forward recommendations suggesting that all relationships with research sponsors be annually reported to the researcher's institution regardless of the amount of money involved.[2] This is, to some extent, an acknowledgement that

1. Kevin P. Weinfurt, Mark A. Hall, Nancy M.P. King, Joelle Y. Friedman, Kevin A. Schulman & Jeremy Sugarman, *Disclosure of Financial Relationships to Participants in Clinical Research,* 361 NEW ENG. J. MED. 916, 916-21 (2009).

2. AAMC-AAU Advisory Committee on Financial Conflicts of Interest in Human

relationships that have no currently determinable monetary value, such as an equity interest in a start-up company with no current assets, can be of great value once a biomedical product is produced and patented. But, it is also evidence of a growing awareness that relationships that involve relatively small amounts of money can pose risks to patients and human subjects.

This recognition of the potential corrosive effects of small gifts has a recent parallel on the treatment side of health care. In the last decade, many health care institutions have adopted a variety of measures to restrict the activities of representatives of pharmaceutical companies within their institutions. In many hospitals, pharmaceutical representatives may no longer purchase lunch for meetings, pay for physicians to attend meetings, offer dinners, or provide a variety of other items they used to parcel out such as pens, pads, and occasionally more substantial items such as stethoscopes. Such gratuities were shown to regularly influence prescribing behaviors. But, the regulating of small amounts of money on the research side is far more difficult because such funds are not presented as gifts but are classified as consulting fees, speaker fees, or reimbursement for expenses incurred in recruiting subjects.

Institutional conflict of interest committees and IRBs seldom try to prohibit such income because they may be accused of prohibiting payment for services. Thus, these committees often discharge their responsibility to protect the human participants of research by requiring that the physician disclose to the patient in the consent form that he or she has a relationship with the sponsoring company. But, of what use can such a disclosure possibly be? Standards regarding the relationships of clinician-researchers to sponsoring companies cannot be improved by introducing a "buyer beware" approach. Patients considering enrolling in research are not usually positioned to determine whether the physician recruiting them or the principal investigator named in the consent form is compromised by their consulting relationships. Requiring disclosure may help all involved to feel more ethical but it is unlikely to make anyone so.

## II. PROMOTING PROFESSIONALISM

Relationships between clinicians who participate in research and the sponsoring companies need to be of the caliber that inspire rather than undermine confidence in the research enterprise. While taking consulting fees in relatively small amounts can be seen as making something of

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Subjects Research, *Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research* (Feb. 2008), *available at* https://services.aamc.org/publications/showfile.cfm?file=version107.pdf&prd_id=220&prv_id=268&pdf_id=107.

nothing, such exchanges can threaten the integrity of doctor-patient and investigator-patient relationships. Physicians who lack appropriate expertise may become involved in the recruitment of participants to sponsored studies, their prescribing or device utilization patterns may become biased, and patients could find themselves recruited to studies which seem to be a poor fit.

To return to our opening image, what would we like our imaginary committee to do? It is not obvious how regulatory apparati can restore a sense of integrity and professionalism to a profession. Almost by definition, a profession should be self-regulating and set its own standards. In this case, it seems that the professions must work to overcome a sense of entitlement that seems to underlay this problem. Too often, professionals come to see various "perks" as simply something that should come their way but which they simultaneously see as beneath their notice and unable to influence them.

Perhaps the future will require that professionals come to see their time as entirely devoted to their profession and only to be compensated through their home institutions. This would not prohibit these professionals from consulting with private industry, but any compensation would be payable to their home institution, whose time the company is seen to be taking. Of course, this will require increased diligence to safeguard institutional integrity, but that is beyond our present scope.